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BIOTECHNOLOGY COMPETITIVENESS ACT OF 1987

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Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 1966]

The Committee on Labor and Human Resources, to which was referred the bill (S. 1966) to amend the Public Health Service Act to improve information and research on biotechnology and the human genome, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

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I. SUMMARY OF THE BILL

The Biotechnology Competitiveness Act of 1987, S. 1966, amends the Public Health Service Act (PHSA) and makes additional provisions as follows:

1. *National Center for Biotechnology Information.*—A center to be located in the National Library of Medicine of the National Institutes of Health, is to be created. NLM will be responsible for coordinating a major initiative aimed at improving databases and re-

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source information in biotechnology. The authorization level will be $10,000,000 each of the fiscal years 1989 through 1993.

2. *National Biotechnology Policy Board and Advisory Panel.*—A board is to be created to review and appraise various Federal programs and activities involving biotechnology, and to make recommendations on a number of issues related to biotechnology. These include the issues of technology transfer, United States competitiveness, training of pertinent personnel, regulatory policies, and promotion of biotechnology-related research. The board will present reports to the President and to the Congress on a regular basis—the first, by January 31, 1990, and thereafter by January 31 of each even-numbered year.

A panel will be created to examine and make recommendations on subjects related to mapping and sequencing the human genome. These include the following: The appropriate strategy needed to map and sequence; research and development objectives needed to assure the United States status as a leader in human genome research; issues related to information ownership; and interagency cooperation. The panel will submit the first report to the Board no later than 18 months after this proposed legislation becomes law, and subsequent reports as the panel judges necessary, or on demand of the Board.

3. *Congressional Bioethics Board.*—The Board shall review the reports prior to publication and comment where appropriate on ethical concerns raised by the development or application of the technology.

II. Background and Need for Legislation

The Biotechnology Competitiveness Act of 1987 creates a national center to support the development of improved and enhanced database services related to biotechnology. This Center will be located within the National Library of Medicine (NLM) of the National Institutes of Health (NIH). Recent developments in molecular biology, principally recombinant DNA and hybridoma technologies, have led to what has been described as a "biotechnology revolution." Biotechnologies have a wide range of applications in numerous areas including human health and agriculture. The United States, through Federal support of NIH, has supported much of the research responsible for these revolutionary developments, and is in a position to capitalize on the biotechnology industry.

Important components of biotechnology include the need for database and repository services to store, catalog, and disseminate information. Data currently are accumulating at a pace which is too great to be supported by existing computer database and repository systems. In addition, many of the existing databases are highly specialized and are incompatible with one another. These inadequacies prevent many researchers from having access to important genetic data, resulting in replication of research efforts which have been done already. If a major effort at coordinating biotechnology-related computer databases and information resources is not initiated, such problems will worsen as the quantity of genetic data continues to accumulate rapidly.

The United States Federal Government owns most of the existing biotechnology-related databases and repositories. NIH administers and funds or co-funds many of these databases and repositories. NLM of NIH serves as a resource for the largest quantity of available medical information worldwide, and has been referred to as "the foremost biomedical communications center in the world." The superior status of NLM in the field of biomedical communications, service and information research, highly qualifies it for coordinating and developing computer databases and information resources needed to support biotechnology.

NLM recently initiated projects aimed at overcoming database and information resource inadequacies related to biotechnology. NIH was provided $3,830,000 in the FY 1988 appropriation bill to support a new National Center for Biotechnology Information in NLM. S. 1966 would give this Center permanent authority to support this biotechnology-related initiative.

S. 1966 establishes a National Biotechnology Policy Board and an Advisory Panel, both of which will be made up of representatives from Federal agencies, the research community, and private industries involved in biotechnology activities. Advances in biotechnology will require the participation of a large and diverse group of participants, and will present a wide range of policy issues. The National Policy Board should be very helpful in addressing these biotechnology-related issues.

The Advisory Panel will address policy issues related to the human genome. This panel will focus on specific research policy issues presented by human genome research activities. Recent advances in biomedical research and technologies have made it possible for scientists to discover the entire genetic makeup of humans. This can be done by locating the estimated 100,000 functional units of the human genome known as genes (mapping), and determining the order of the 4 different chemicals (nucleotides bases) making up each gene, which is known as sequencing. A gene may contain from about 1,000 to more than 1,000,000 nucleotide bases. Although technology is currently under development to map and sequence the human genome, additional developments are needed to most efficiently and expeditiously perform this monumental task.

Information obtained from mapping and sequencing the human genome would be extremely beneficial in the search for the causes, treatment, and prevention of genetic diseases in humans, which total some 4,000 known conditions. This prospect is especially significant because, in most cases, no cure is available for genetic diseases and doctors can offer at most only palliative treatments. Human genome mapping and sequencing information would serve as an important tool in the pursuit of a basis for human diseases and developmental processes. However, scientists disagree on which approach should be taken to map and sequence the human genome.

Several Federal agencies, including NIH, DOE and NSF, are currently funding research related to mapping and sequencing the human genome. Representatives from each of these agencies will sit on the National Advisory Panel on the Human Genome. In addition, individuals representing private industry, the university research community, and biomedical ethics concerns will be on the

Panel to address the scientific, legal and other policy issues related to mapping and sequencing the human genome.

III. TEXT OF THE BILL AS REPORTED

[S. 1966, 100th Cong., 2d sess.]

A BILL To amend the Public Health Service Act to improve information and research on biotechnology and the human genome, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Biotechnology Competitiveness Act of 1987".

TITLE I—NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

SEC. 101. FINDINGS.

Congress finds that—

(1) biotechnologies help to advance our understanding of the composition of human chromosomes and cells, and our knowledge of fundamental human development and disease process;

(2) information on the map and sequence of the human genome, as well as the many other important fields of biotechnology research, is accumulating faster than can be reasonably assimilated by present methods;

(3) it is essential that advances in information science and technology be made so that this vast new knowledge can be organized, stored and utilized;

(4) there are numerous independent computer data bases that hold portions of the burgeoning biotechnological discoveries and such data bases lack common technology, central coordination, and adequate support;

(5) it is important that information on research in biotechnology be available to researchers to allow coordination of the research efforts ongoing in public and private sector laboratories;

(6) the National Library of Medicine of the National Institutes of Health is highly suited, by virtue of its preeminence in the field of biomedical communications, service, and information research, to facilitate the rapid advance of biotechnology through information transfer; and

(7) a biotechnology information initiative could take advantage of the unique facilities of the National Library of Medicine to develop new communications tools and serve both as a repository and as a center for the distribution of molecular biology information to researchers and health practitioners.

SEC. 102. NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION.

Part D of title IV of the Public Health Service Act (42 U.S.C. 286 et seq.) is amended by adding at the end the following new subpart:

"Subpart 3—National Center for Biotechnology Information

"SEC. 478. NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION.

"(a) ESTABLISHMENTS.—To focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology research by information systems, and to support and enhance the development of new information technologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the 'Center') in the National Library of Medicine.

"(b) FUNCTIONS.—Through the Center and subject to section 465(d), the Secretary shall—

"(1) coordinate the design, development, implementation, and management of automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human, animal, and plant molecular biology, biochemistry, and genetics;

"(2) [perform research] *conduct a research program* into advanced methods of computer-based information processing capable of representing and analyzing the vast number of biologically important molecules and compounds *using Center capabilities, as well as those in Federal, university, and private research laboratories*;

"(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) methods described in paragraph (2);

"(4) coordinate the efficient input of information regarding biotechnology from all government agencies [and agency grantees,] *as well as agency grantees and contractors,* and where applicable, inform granting agencies of duplications of research efforts;

"(5) encourage the input of information regarding biotechnology from the private sector, including professional scientific societies, foundations, and companies;

"(6) coordinate biotechnology research information provided by the center and other sources, including the biotechnology industry, other government agencies, and the private sector (including professional scientific societies, foundations, and companies); and

"(7) coordinate, to the maximum extent practicable, efforts to gather biotechnology information on an international basis.

"(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of the fiscal years 1989 through 1993. Funds appropriated under this subsection shall remain available as specified in appropriations acts.".

TITLE II—NATIONAL BIOTECHNOLOGY POLICY BOARD AND ADVISORY PANEL

Subtitle A—National Biotechnology Policy Board

SEC. 201. ESTABLISHMENT, MEMBERSHIP, CHAIRMANSHIP, MEETING.

(a) ESTABLISHMENT.—There is established in the Executive branch of the Federal government a National Biotechnology Policy Board (hereinafter in this title referred to as the "Board").

(b) MEMBERSHIP.—The membership of the Board shall consist of the following individuals or their designees:

(1) The Director of the National Institutes of Health.

(2) The Director of the National Science Foundation.

(3) The Secretary of Agriculture.

(4) The Secretary of Commerce.

(5) The Secretary of Defense.

(6) The Secretary of Energy.

(7) The Commissioner of the Food and Drug Administration.

(8) The Administrator of the Environmental Protection Agency.

(9) The Director of the Office of Science and Technology *Policy,* who shall serve as an ex-officio, nonvoting member of the Board.

(10) The Director of the Office of Management and Budget, who shall serve as an ex-officio, nonvoting member of the Board.

(11) Four individuals representing the university research community, to be recommended by the National Academy of Sciences and appointed by the President, with the advice and consent of the Senate, with members appointed within 90 days after the date of enactment of this Act.

(12) Four individuals representing diverse United States biotechnology-related industries to be appointed by the President, after consultation with relevant groups, with the advice and consent of the Senate, with members appointed within 90 days after the date of enactment of this Act.

(13) One individual with expertise in biomedical ethics, to be recommended by the National Academy of Sciences and appointed by the President, after consultation with relevant groups, with the advice and consent of the Senate, with such member being appointed within 90 days after the date of enactment of this Act.

(14) One individual representing national foundations, medical institutes, and other philanthropic organizations involved in biomedical research, to be recommended by the National Academy of Sciences and appointed by the President, after consultation with relevant groups, with the advice and consent of the Senate, with such member being appointed within 90 days after the date of enactment of this Act.

(c) TERM OF SERVICE.—

(1) IN GENERAL.—Except as provided in paragraph (3), Board members appointed under paragraphs (11) through (14) of subsection (a) shall serve 4-year terms and shall serve until a successor for such member is appointed and confirmed.

(2) VACANCIES.—Any individual appointed to fill a vacancy on the Board that occurs prior to the expiration of the term for which the predecessor was appointed shall be appointed for the remainder of such term.

(3) STAGGERED TERMS.—Terms of the initial Board members appointed under paragraphs (11) and (12) of subsection (a) shall be determined by the President at the time of the appointment in accordance with the following:

(A) One industry and one university representative shall be appointed for a term of 4 years.

(B) One industry and one university representative shall be appointed for a term of 3 years.

(C) One industry and one university representative shall be appointed for a term of 2 years.

(D) One industry and one university representative shall be appointed for a term of 1 year.

(4) REAPPOINTMENT.—Nongovernment Board members may be reappointed by the President with the advice and consent of the Senate.

(d) CHAIRMAN.—

(1) SELECTION.—The members of the Board shall select a Chairman from among its members to serve for a term of 2 years.

(2) VACANCY.—In the event of a vacancy in the Chairmanship, the Board shall elect a Chairman to serve the remainder of the unexpired term.

(3) RE-ELECTION.—Chairman may be re-elected by the members of the Board.

(e) MEETING.—

(1) INITIAL MEETING.—Within 90 days after the approval by the Senate of the last member of the initial Board, the Board shall meet to elect a Chairman.

(2) SUBSEQUENT MEETINGS.—The Board shall meet at least twice a year.

SEC. 202. DUTIES AND FUNCTIONS.

The Board shall—

(1) review and appraise the various programs and activities of the Federal Government relating to biotechnology, including the amount and type of biotechnology-related research conducted or funded by Federal agencies,

(2) review and appraise the extent and nature of privately-funded biotechnology activities, including *non-confidential* research, both basic and applied, and the development of commercial biotechnology-related industries and products;

(3) submit recommendations to the President and Congress, where appropriate, concerning—

(A) policies that will enhance the efficient and timely advance of basic and applied biotechnology-related research;

(B) methods to enhance the competitiveness of the United States in the development of commercial biotechnology-related industries and products;

(C) policies that will ensure the training of sufficient numbers of scientists, engineers, and laboratory personnel for the continued leadership of the United States in biotechnology-related basic and applied research and the development of the biotechnology industries of the United States;

(D) Federal participation in proposed cooperative research initiatives involving governmental and private entities;

(E) regulatory policies that affect biotechnology industries and the products thereof; and

(F) policies that will enhance the transfer of technology from university and Federal research laboratories to commercial laboratories so as to allow the efficient and timely commercialization of Federally funded discoveries.

SEC. 203. REPORTS.

Not later than January 31, 1990, and not later than January 31, of each even-numbered year thereafter, the Board shall submit, to the President and to the Congress a report that contains recommendations described in section 2(3). The Board shall submit additional reports and recommendations as the Board considers necessary, or on the demand of the President or Congress. Reports shall be published and made available to the public.

SEC. 204. STAFF AND PERSONNEL.

(a) EXECUTIVE DIRECTOR.—

(1) APPOINTMENT.—The Board shall appoint an Executive Director, who shall serve at the pleasure of the Board.

(2) DUTIES.—The Executive Director shall report directly to the Board and perform such duties and functions as the Board may prescribe.

[(3) COMPENSATION.—The Executive Director shall be compensated at a rate not to exceed that provided for a postion at level 4 of the Executive Schedule under section 5315 of title 5, United States Code.]

(b) OTHER PERSONNEL.—The Board may employ such other officers and employees as may be necessary to carry out the duties and responsibilities of the Board and its advisory panel[, at rates not to exceed the rates prescribed for grade GS–14 of the General Schedule in section 5332 of title 5, United States Code.].

(c) VOLUNTARY SERVICES.—Notwithstanding section 665(b) of title 31, United States Code, the Board may accept and employ voluntary and uncompensated services in furtherance of the purposes of the Board.

SEC. 205. COORDINATION WITH OTHER AGENCIES.

(a) IN GENERAL.—The Board shall work in consultation with other Federal agencies (including such agencies represented on the Board) and in consultation with other Boards and Commissions as may be appropriate, including the Biomedical Ethics Board and the New Products Research Board.

(b) BIOMEDICAL ETHICS BOARD.—The Biomedical Ethics Board shall review, prior to publication and as apppropriate, comment on reports issued by the Board and the advisory panels established pursuant to subsection (d)(2).

[(b)] *(c)* INFORMATION.—Each department, agency, and instrumentality of the Executive branch of the Federal government and each independent agency and other governmental organization, including the Office of Technology Assessment, shall furnish the Board with such information as the Board shall consider necessary and appropriate to assist the Board in carrying out its functions and duties.

[(c)] *(d)* CONSULTATIONS.—The Board may—

(1) utilize the services of consultants;

(2) establish advisory panels; and

(3) to the extent practicable, consult with—

(A) State and local governments;

(B) appropriate professional and industry groups;

(C) representatives of university, industry, labor, consumer and other public interest groups; and

(D) individuals as is appropriate.

[(d)] *(e)* HEARINGS.—The Board may hold hearings and meetings in various parts of the United States as may be appropriate in carrying out the functions and duties of the Board.

[(e)] *(f)* DUPLICATION AND REIMBURSEMENT.—

(1) DUPLICATION.—The Board shall utilize, to the fullest extent possible, the services, personnel, equipment, facilities, and information of public and private agencies and organizations, and individuals, in order to avoid duplication of effort and expense.

(2) REIMBURSEMENT.—The Board may transfer funds made available pursuant to this title to other Federal agencies as may be appropriate to reimburse such agencies for the utilization of agency personnel, services, facilities, equipment and information.

SEC. 206. COMPENSATION OF MEMBERS.

(a) NONGOVERNMENT MEMBERS.—Each member of the Board that is not otherwise in the service of the Federal government shall receive a sum equivalent to the compensation provided at level IV of the Executive Salary Schedule under section 5315 of title 5, United Stated Code, prorated on a daily basis for each day spent in service to the Board, and shall be paid actual travel expenses, and per diem in lieu of subsistence expenses in accordance with section 5703 of title 5, United States Code, when such member is away from the members usual place of residence.

(b) GOVERNMENT MEMBERS.—Each member of the Board that is otherwise in the service of the Federal Government shall serve without compensation in addition to that received for such other service, but while engaged in the work of the Board, such member shall be paid actual travel expenses, and per diem in lieu of subsistence expenses in accordance with subchapter I of chapter 57 of title 5, United States Code, when away from the members usual place of residence.

SEC. 207. AUTHORIZATION OF APPROPRIATION.

There are authorized to be appropriated to carry out this title $2,000,000 in fiscal year 1989, $2,500,000 in each of the fiscal years 1990 and 1991, and $3,000,000 in each of the fiscal years 1992 and 1993.

Subtitle B—Human Genome Research and Development

SEC. 211. FINDINGS.

Congress finds that—

(1) knowledge relating to the location and sequences of genes on human chromosomes and those other organisms will enable more rapid elucidation of the basis for developmental processes and for human disease;

(2) comprehensive understanding of human genetic make-up, and the genetics of other organisms, will enhance our ability to develop methods for the prevention and treatment of disease states;

(3) advances in biomedical research and technologies have enabled rapid progress in the localization of genes to specific human chromosomes;

(4) a number of Federal agencies (including the National Institutes of Health, the Department of Energy, and the National Science Foundation) are presently funding research related to the mapping and sequencing of genes within the human genome or basic biomedical research, or the development of new technologies and instruments for this research; and

(5) in order to most efficiently expend research funds, and to most expeditiously advance our understanding of human genetics, it is essential that the agencies involved coordinate their research efforts.

SEC. 212. NATIONAL ADVISIORY PANEL ON THE HUMAN GENOME.

(a) PURPOSE.—The purpose of this section is to establish a National Advisory Panel on the Human Genome that shall coordinate—

(1) national activities to ensure the construction of maps of human chromosomes and DNA of other organisms to be used as powerful research tools for biomedical research; and

(2) the development of new tools to analyze DNA, in cooperation with philanthropic, companies, and other private sector interests.

(b) ESTABLISHMENT.—There is established, as an advisory panel to the Board established in subtitle A, a National Advisory Panel on the Human Genome (herinafter referred to in this subtitle as the "Panel") to advise the Board on matters concerning the mapping and sequencing of human genome.

(c) MEMBERSHIP.—The Panel shall consist of the following individuals, or the designees of such individuals—

(1) the Secretary of Energy;

(2) the Director of the National Institutes of Health;

(3) the Director of the National Science Foundation.

(4) the Director of the National Library of Medicine;

(5) four individuals representing private industry, to be appointed by the President, after consultation with relevant groups, with the advice and consent of the Senate, with members appointed within 90 days after the date of enactment of this Act, but who shall not be members of the Board;

(6) four individuals representing the university research community, to be recommended by the National Academy of Science and appointed by the President, with the advice and consent of the Senate, with members appointed within 90 days after the date of enactment of this Act, but who shall not be members of the Board;

(7) one individual with expertise in biomedical ethics, to be recommended by the National Academy of Sciences and appointed by the President, with the advice and consent of the Senate, with such member being appointed within 90 days after the date of enactment of this Act; and

(8) one individual representing national foundations, medical institutes, and other philanthropic organizations involved in biomedical research, to be recommended by the National Academy of Sciences and appointed by the President, with the advice and conent of the Senate, with such member being appointed within 90 days after the date of enactment of this Act.

(d) CHAIRMEN.—The Panel shall be cochaired by the Secretary of Energy and the Director of the National Institutes of Health or the designees of such.

(e) FUNCTIONS.—The Panel shall—

(1) identify the optimal strategy for mapping and sequencing the human genome utilizing for guidance information and recommendations from previous reports, including those of the Office of Technology Assessment and the National Academy of Sciences;

(2) determine research and development goals that will ensure United States leadership in human genome research;

(3) ensure the quality of scientific and technical work, and establish standards for the collection and storage of data and materials;

(4) assess the need for common research resources such as materials repositories and new databases;

(5) monitor relevant research programs supported by Federal agencies and private funding sources;

(6) identify commercial opportunities arising from national research programs;

(7) oversee interagency cooperation through data-sharing, joint sponsorship of meetings, joint funding of research resources, and communication of annual budget plans;

(8) assess the need and benefit of international cooperation in mapping and sequencing the human genome; *and*

[(9) evaluate the ethical considerations of research and development of products from mapping and sequencing the human genome; and]

[(10)] *(9)* evaluate patent rights and ownership of data on the human genome, and provide advice to interested Federal agencies, the scientific community, and private industry.

(f) REPORTS.—Not later than 18 months after the date of enactment of this section, the Panel shall submit to the Board a report that contains recommendations based on the functions of the Panel under section 212(e). Additional reports shall be submitted to the Board as the Panel considers necessary, or on demand of the Board.

(g) BIOMEDICAL ETHICS BOARD.—The Biomedical Ethics Board shall review, and as appropriate, comment on the ethical and social implications of human genome research.

TITLE III—BIOMEDICAL ETHICS BOARD REAUTHORIZATION

SEC. 301. BIOMEDICAL ETHICS BOARD REAUTHORIZATION.

Subsection (e) of section 381 of the Public Health Service Act (42 U.S.C. 275(e)) is amended to read as follows:

"(e) To enable the Board and the Committee to carry out their functions, there are authorized to be appropriated $2,000,000 for fiscal year 1989, $2,500,000 for fiscal year 1990, and $3,000,000 for fiscal year 1991.".

IV. COMMITTEE VIEWS

The Biotechnology Competitiveness Act of 1987 provides new authority under the Public Health Service Act to promote biotechnology research and product development. Through this legislation, the Committee affirms its commitment to the enhancement and facilitation of biotechnology research, especially as it relates to the effort to map and sequence the human genome.

The Office of Technology Assessment (OTA) has defined biotechnology as "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants and animals, or to develop micro-organisms for specific uses." In the early 1960s, scientists first delineated the structure of DNA (deoxyribonucleic acid), the chemical matrix which makes up the genetic code of humans and all plants and animals. In 1973 scientists for the first time transferred DNA from one organism to another. Since then, recombinant DNA and associated technologies have been the focus of intensive research and the source of previously unimagined biomedical and agricultural advances. It is widely believed that techniques of biotechnology, especially those utilizing recombinant DNA, will greatly enhance the diagnosis and treatment of human disease, food production and processing, chemical synthesis, energy production and waste management. Applications in electronics and materials development are also anticipated.

In recent years, the possibility of unravelling the genetic code of humans and other species has advanced greatly. Progress has been achieved in determining the physical location of the thousands of genes located on the twenty-three pairs of human chromosomes. Such a map will significantly enhance our ability to determine carriers of genetic diseases, and better enable physicians and scientists to predict who may suffer from illnesses such as heart disease and cancer. Determining the chemical structure of the human genome—the sequence of nucleotide base pairs that comprise each

gene—will greatly enhance our ability to determine the exact genetic differences that cause or lead to disease. Information on the genetic code of other plant and animal organisms will enhance the understanding of human disease. All this information may lead to specific genetic therapy, an intervention thought to be impossible until recent years.

The effort to completely map the location of the thousands of human genes, and determine the sequence of the estimated three billion base pairs of the human genome will require several years and several groups of scientists to achieve. Estimates of the cost in current dollars range up to $3 billion to achieve a complete map and sequence of the human genome. Reports recently issued by the OTA and the National Research Council strongly support the effort to first map and then sequence the human genome. The scientific community and the biotechnology industry here in the United States and in many other countries have reached a clear consensus on the importance and necessity of undertaking this effort.

Biotechnology research in this country has largely been supported by the National Institutes of Health (NIH), although other federal agencies such as the Departments of Agriculture, Defense and Energy and the National Science Foundation have also devoted considerable resources in this area.

Hundreds of biotechnology companies have been initiated over the past two decades, many in partnership with large pharmaceutical companies, and major research universities and academic health centers, with the intent of developing new products using recombinant DNA, hybridoma and other biotechnologies. From small entrepreneurial start-ups, a few biotechnology companies have grown tremendously in size, sales and market valuation. The Department of Commerce estimates the market for biotechnology products will exceed $40 billion by the year 2000, and many believe this estimate to be conservative.

Other countries have recognized the importance of biotechnology in the international economy of the present and future. Japan's Ministry of International Trade and Industry (MITI) has desingated biotechnology, microelectronics and new materials as the "Basic Technologies for Future Industries". Japanese eforts have centered on strategic planning and cooperation between government, universities and industry. Japanese scientists have already begun the project to map and sequence the human genome. A recent OTA report stated that Japan will be the most serious competitor of the U.S. in the commercialization of biotechnology, including pharmaceuticals.

Both France and West Germany have established national biotechnology programs. British pharmaceutical companies and universities are conducting cooperative research under the coordination of the Department of Trade and Industry.

The Committee strongly believes that if the United Staes is to maintain its world leadership in biotechnology, not only should basic research receive generous support, but government at all levels should work with the biotechnology industry and scientific investigators to facilitate the development of products from public and private research efforts. As a recent report from the National Academy of Engineering ("The Technical Dimensions of Interna-

tional Competitiveness", a Report to the Council of the National Academy of Engineering, 1988) has conveyed, ". . . government policies [should] be constantly reviewed to ensure that they not only achieve the desired social, political, and national security purposes, but also support—or at least not impair—our international competitiveness."

NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

The first title of the legislation establishes the National Center for Biotechnology Information at the National Library of Medicine. The Committee recognizes the need to focus and expand the collection, storage, retrieval and dissemination of data concerning biotechnology information. The National Library of Medicine has in recent years taken a leadership position in developing new computer databases containing extensive information on biotechnology research, and in coordinating access to existing computer databases. The Committee supports the continuation of these efforts and recognizes the need for greater resources.

The National Center for Biotechnology Information will coordinate the further design, development and management of automated systems for information on human, animal and plant molecular biology, biochemistry and genetics. The Center will also conduct research into advanced methods of information processing using Center capabilities as well as those in university, private and federal research laboratories. The Center will be responsible for coordinating access to computer databases in this and other countries, and for developing computer databases from existing hard copy information. The Center will also serve to coordinate the input and access to information regarding biotechnology from federal and state government agencies, agency grantees and contractors, and where possible inform granting agencies of duplication of research efforts. Finally, the Center will encourage cooperation between government and private sector sources of biotechnology information, including professional scientific societies, foundations and companies.

Data concerning the mapping of the human genome and those of other life forms are quite extensive. Elucidation of this information is just the first step toward greater understanding of inheritance and genetic disease; researchers must be able to access the information easily. The National Library of Medicine has already developed automated systems for accessing this information contained in its own databases and those sponsored by universities, private concerns and other countries. Information on the DNA sequence of the human genome and for other animals and plants is accumulating exponentially, and requires sophisticated automated systems for collection and retrieval. Again, the National Library of Medicine has had considerable involvement in this area.

To effectively utilize all the information to be obtained from the effort to map and sequence the entire human genome, though, greater resources need to be allocated for computer databases management. The Committee recognizes that the National Library of Medicine is the most qualified government organization to handle this responsibility, because of its demonstrated expertise in the

field of biomedical communications, service, information research and understanding of the needs of researchers. Establishment of the National Center for Biotechnology Information confirms the confidence of the Committee in the National Library of Medicine in the efforts to help advance our understanding of the composition of human chromosomes, and our knowledge of fundamental human development and disease processes.

S. 1966 authorizes $10 million for each of the fiscal years 1989 through 1993.

NATIONAL BIOTECHNOLOGY POLICY BOARD

The second title of this legislation initiates the National Biotechnology Policy Board in the Executive Branch of the federal government, with representatives from government, the biotechnology industry, the university research community, and foundations engaged in biotechnology research. An expert in biomedical ethics will also be included. The purpose of this Board is to provide recommendations to the President and Congress on the optimal policies for support and coordination of biotechnology research and product development. The Committee recognizes the need for coordinated policy advice for discussions between the government and private sectors and further believes that policy decisions, especially concerning resource allocation, should be guided by expert recommendations.

The purpose of this Board shall be to review the various activities relating to biotechnology research and product development supported or conducted by federal agencies and private concerns. The intent of this review shall be to report recommendations to the President and Congress on policies that will: (1) enhance the conduct of basic and applied biotechnology research; (2) improve the competitiveness of the United States in the development of commercial biotechnology products and industries; (3) ensure the training of sufficient numbers of scientists, engineers and laboratory personnel to conduct biotechnology research and product development; (4) promote cooperation and technology transfer between federal agencies, federal and state agencies, and government and private concerns involving biotechnology research and product development; and (5) improve regulations that impact upon biotechnology.

To assure thorough and proper consideration of ethical issues surrounding biotechnology research and product development, any and all reports from the Board shall be referred to the Congressional Biomedical Ethics Board for comment and review.

Overall, the Committee is confident in the ability of the Environmental Protection Agency and other federal regulatory agencies to monitor the safety of biotechnology products and genetically altered organisms. A recent report from the National Academy of Sciences ("Introduction of recombinant DNA-Engineered Organisms into the Environment: Key Issues", National Academy Press, 1987) concluded, "There is no evidence that unique hazards exists either in the use of R-DNA techniques or in the movement of genes between unrelated organisms . . . R-DNA techniques constitute a powerful and safe new means for the modification of orga-

nisms." The report stated further, "The scientific community urgently needs to provide guidance to both investigators and regulators in evaluating planned introductions of modified organisms from an ecological perspective." The Committee urges the Board to follow these recommendations in considering biotechnology research and products derived thereof.

The Board shall review the regulatory function and policies of the Environmental Protection Agency, the Food and Drug Administration and other federal and state agencies to determine their appropriateness toward assuring safety of biotechnology research and product development. The Committee strongly urges the Board to carefully evaluate the safety concerns of biotechnology, especially involving research and products developed from recombinant DNA technology.

The membership of the Board shall consist of the Director of the National Institutes of Health, The Director of the National Science Foundation, the Secretary of Agriculture, the Secretary of Commerce, the Secretary of Defense, the Secretary of Energy, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Director of the Office of Science and Technology Policy, and the Director of the Office of Management and Budget, or their designees. In addition, the President shall appoint from a list of nominees prepared by the National Academy of Sciences, four individuals representing the university research community. The President shall also appoint four individuals representing the biotechnology industry, one individual with expertise in biomedical ethics and one individual representing national foundations, medical institutes and other philanthropic organizations. The Chairman of this Board shall be selected from the members of the Board, by the members of the Board. The Committee strongly supports the concept of a biotechnology policy board that has representation from all sectors, private and public, with an interest and responsibility in biotechnology research and product development.

After referring reports to the Congressional Biomedical Ethics Board, The Biotechnology Board shall report to the President and to Congress not later than January 31, 1990, and every two years after this date. The referral of reports to the Congressional Biomedical Ethics Board prior to publication should allow for their thorough review. The Committee does not intend for reports to be delayed by review of the Congressional Biomedical Ethics Board; publication may take place prior to completion of the review. The Board may submit more frequent comments and reports as the Board considers necessary. All reports of the Board shall be published and made available to the public. To support the administrative function of the Board, $2 million is authorized in fiscal year 1989, $2.5 million in each of fiscal years 1990 and 1991, and $3 million in each of the fiscal years 1992 and 1993.

NATIONAL ADVISORY PANEL ON THE HUMAN GENOME

The legislation also establishes a National Advisory Panel on the Human Genome as an advisory panel to the National Biotechnology Policy Board. Recognizing the great interest in the scientific

and biotechnology communities concerning a map and sequence of the full human genome, the Committee considers policy direcion to be the first step which will guide appropriation of large scale resources for this project. Recent reports from the Office of Technology Assessment and the National Research Council strongly support this effort, calling for allocation of considerable federal resources and involvement of government and private agencies in formulating policy direction. The Committee strongly supports the goal of achieving a map and base sequence of the entire human genome as soon as possible. The Committee also agrees with the recommendation of both the Office of Technology Assessment and National Research Council reports that funding for this effort should not detract from currently funded biomedical research areas.

The Genome Panel shall consist of the Secretary of Energy, the Director of the National Institutes of Health, the Director of the National Science Foundation and the Director of the National Library of Medicine, or their designees, along with four individuals representing the biotechnology industry, four individuals representing the research community, one individual with expertise in biomedical ethics and one individual representing national foundations, medical institutes and other philanthropic organizations involved in biomedical research. The Panel shall be co-chaired by the Secretary of Energy and the Director of the National Institutes of Health, or their designees.

While a single lead agency would be ideal, the Committee recognizes the considerable current funding and commitment to achieve a map and sequence of the human genome of both the Department of Energy and the National Institutes of Health and considers the co-chair designation optimal. This arrangement will draw upon the unique expertise and resources of the national laboratories supported by the Department of Energy, and the strength of peer-review biomedical research projects supported by the National Institutes of Health. Inclusion of representatives from both private industry and the biomedical research community should greatly expand the understanding and sensitivity of the Panel to the importance of these non-government sectors in this scientific effort.

As with the National Biotechnology Policy Board, reports developed by the Genome Panel shall be referred to the Congressional Biomedical Ethics Board for review and comment on the ethical and social implications of human genome research.

Not more than 18 months after the date of enactment of S. 1966, the Genome Panel shall submit its first report to the National Biotechnology Policy Board concerning the optimal plan for completing the project to map and sequence the human genome. The Committee strongly encourages the Panel to carefully consider how best to provide resources for this project, and how best to assure United States competitiveness in achieving this goal.

BIOMEDICAL ETHICS BOARD REAUTHORIZATION

The third title of the legislation reauthorizes the Biomedical Ethics Board. $2 million is authorized to be appropriated in fiscal year 1989, $2.5 million in fiscal year 1990, and $3 million in fiscal year 1991. The Committee strongly encourages the Board to initi-

ate and complete its mandated report on research and development in genetic engineering, including activities in recombinant DNA technology. The Committee further encourages the Board to objectively assess all ethical issues surrounding research in human genetics, and provide clear, unbiased recommendations to Congress on the optimal means to support this research.

The Committee strongly supports the continued advancements in biotechnology in general and, specifically, the development of a map of the human genome. The Committee also recognizes that this new technology raises a number of legal, social, ethical and moral questions. Development of some gene therapies, for example, could affect the diversity of the human gene pool. Therefore, all implications of these therapies should be carefully considered.

There may also be problems surrounding access to this new technology. While it may provide opportunities to significantly improve the quality of life, decrease suffering and increase of the productivity of mankind, it will initially be expensive. All in society should have equal access to the benefits of these advancements.

Another source of concern is raised regarding who will have access to genetic information. Some suggest that genetic screening may allow children to be "marked" from birth as having certain potentials, thus possibly limiting their educational and career options. It is important to consider who should have access to this information (the government, employers, schools, insurance companies, etc.) and what should be the permissible uses of the information.

For these reasons and others, the Committee has required the reports of the National Biotechnology Policy Board and the National Advisory Panel on the Human Genome be forwarded to the Congressional Biomedical Ethics Board for review prior to publication. The Committee intends for the Congressional Biomedical Ethics Board to continually review and monitor this area to provide Congress and the public with periodic summaries of the legal, social, ethical and moral questions raised.

V. Committee Action

S. 1966 was considered by the Committee on April 13, 1988, and reported favorably with an amendment by unanimous vote.

VI. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, April 18, 1988.

Hon. Edward M. Kennedy,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 1966, the Biotechnology Competitiveness Act of 1987, as ordered reported by the Senate Committee on Labor and Human Resources on April 13, 1988.

If you wish further details on this estimate, please call me or have your staff contact Lori Housman (226-2820).

Sincerely,

JAMES L. BLUM,
Acting Director.

Attachment.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 1966.
2. Bill title: Biotechnology Competitiveness Act of 1987.
3. Bill status: As ordered reported from the Senate Committee on Labor and Human Resources, April 13, 1988.
4. Bill purpose: The purpose of S. 1966 is to amend the Public Health Service Act to improve information and research on biotechnology and the human genome. This bill would establish the National Center for Biotechnology Information and the National Biotechnology Policy Board and Advisory Council. S. 1966 would also reauthorize the Biomedical Ethics Board. This bill is subject to subsequent appropriations action.

[By fiscal years, in millions of dollars]

	1989	1990	1991	1992	1993
Authorization Levels:					
National Center for Biotechnology Information	10.0	10.0	10.0	10.0	10.0
National Biotechnology Policy Board and Advisory Panel	2.0	2.5	2.5	3.0	3.0
Biomedical Ethics Board Reauthorization	2.0	2.5	3.0	—	—
Total authorization level	14.0	15.0	15.5	13.0	13.0
Total estimated outlays	10.4	14.2	15.4	13.0	13.0

The costs of this bill would fall within budget function 550.

Basis of estimate: The bill estates authorization levels for all of the provisions, The CBO assumes that all authorized amounts are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of historical spending data.

S. 1966 would establish the National Center for Biotechnology Information within the National Library of Medicine. This center would facilitate the integration of biotechnology research through the use of automated information systems. The bill would also reauthorize the Biomedical Ethics Board through fiscal year 1991.

The National Biotechnology Policy Board and the Advisory Panel on the Human Genome would be established under S. 1966. Both federally- and privately-funded biotechnology research would be evaluated by the Board. The Panel, part of the National Biotechnology Policy Board, would advise the Board on progress made towards mapping and sequencing the human genome and would submit a report on their findings to the Board not later than 18 months after the enactment date of this bill.

6. Estimated cost to State and local government: None.
7. Estimate comparison: None.
8. Previous CBO estimate: None.

9. Estimate prepared by: Lori Houseman.
10. Estimate approved by: James L. Blum, Assistant Director for Budget Analysis.

VII. Regulatory Impact Statement

The Committee has determined that there will be minimal or no increase in regulatory burden of paperwork as a direct result of this bill.

VIII. Section-by-Section Analysis

S. 1966—BIOTECHNOLOGY COMPETITIVENESS ACT OF 1987

A BILL To improve information on biotechnology and the human genome, and for other purposes

Section 1. Short title

Section 1 of the bill cites the Act as the "Biotechnology Competitiveness Act of 1987."

Title I—National Center for Biotechnology Information

Section 101. Findings

Section 101 sets forth the findings of Congress. Biotechnologies help promote our knowledge of disease processes and important fundamentals of human development, as well as our understanding of the composition of human chromosomes; human genome mapping and sequencing information, and data on other important fields of biotechnology research are amassing faster than can be reasonably assimilated by current methods; advances in information science and technology must be made in order to organize, store and utilize this vast new knowledge; a number of independent computer databases contain portions of the burgeoning biotechnology discoveries and these databases are deficient in common technology, central coordination, and adequate support; the National Library of Medicine (NLM) of the National Institutes of Health (NIH) is highly suited to facilitate the rapid advance of biotechnology through information transfer, by virtue of its superiority in the field of biomedical communications, service, and information research; a biotechnology information initiative could exploit NLM's unique facilities to develop new communications tools and to serve as a repository, as well as a center for the distribution of molecular biology information to researchers and health practitioners.

Section 102. National Center for Biotechnology Information

Section 102 adds a new "Subpart 3—National Center for Biotechnology Information" (the "Center") to Part D of title IV of the Public Health Service Act (PHSA). New PHSA section 478A establishes in NLM a National Center for Biotechnology Information to focus and expand the collection, storage, retrieval, and dissemination of biotechnology research results by information systems. The Center also will aid and enhance the development of new information technologies to support the understanding of the molecular processes that control health and disease.

New section 478B sets forth the functions of the Center to be implemented by the Secretary of the Department of Health and Human Services (HHS). The Secretary, subject to section 465(d) of PHSA, will coordinate the design, development, implementation, and management of automated systems used to collect, store, retrieve, analyze, and disseminate information related to human, animal, and plant molecular biology, biochemistry, and genetics; perform research related to advanced methods of computer-based information processing capable of representing and analyzing the large number of molecules and compounds of biological importance; permit people involved in biotechnology and research and medical care to use the automated systems and the advance methods mentioned above; coordinate efficient input of biotechnology-related knowledge from government agencies and agency grantees, and inform granting agencies of duplications of research efforts where applicable; encourage entry of biotechnology data from the private sector, including professional scientific societies, foundations and companies; coordinate research information on biotechnology supplied by the Center and other sources; and coordinate, as much as possible, efforts to collect biotechnology information on an international basis.

New section 478C authorizes appropriations of $10,000,000 for each of the fiscal years 1989 through 1993.

TITLE II—NATIONAL BIOTECHNOLOGY POLICY BOARD AND ADVISORY PANEL

SUBTITTLE A—NATIONAL BIOTECHNOLOGY POLICY BOARD

Section 201. Establishment, membership, chairmanship, and meeting

Section 201 establishes in the Executive branch a National Biotechnology Policy Board (the "Board"). The section describes the membership of the Board (4 Directors of Federal Agencies, 4 Secretaries of Departments, 1 Commissioner, the Administrator of 1 Agency, and 10 appointed members), their terms of service, and meeting requirements.

Section 202. Duties and Functions

Section 202 describes the duties and functions of the Board. The Board will review and appraise Federal Government programs and activities involving biotechnology; review and appraise privately-funded activities and the development of commercial industries and products involving biotechnologies; and submit appropriate recommendations to the President and Congress relating to the following: policies that will enhance effective and timely promotion of basic and applied biotechnology-related research; methods to enhance the United States' competitiveness in developing commercial industries and products related to biotechnologies; policies that will assure that an adequate number of scientists, engineers, and laboratory personnel are trained to support the continued leadership of the United States in biotechnology-related research and the development of the biotechnology industries; Federal participation in proposed cooperative research initiatives that relate to governmen-

tal and private entities; regulatory policies that affect biotechnology industries and products; and policies that will enhance technology transfer from university and Federal laboratories to commercial laboratories.

Section 203. Reports

Section 203 directs the Board to submit the first report containing the above-mentioned recommendations to the President and to the Congress no later than January 31, 1990, and subsequent reports no later than January 31 of each even-numbered year.

Section 204. Staff and personnel

Section 204 makes provisions for staff and personnel of the Board. The section provides for an Executive Director and other personnel, as well as voluntary services.

Section 205. Coordination with other agencies

Section 205 permits the Board to consult with other Federal agencies, Boards, and Commissions, including the Biomedical Ethics Board and the New Products Research Board. The section sets forth requirements that each department, agency, and instrumentality of the Executive branch of the Federal government and each independent and other governmental organization should provide the Board with any information the Board believes necessary to perform the functions and duties described in section 202. The Board may also establish advisory panels, hold appropriate hearings and meetings, and use the services of consultants. The Board will be permitted to consult with: State and local governments; appropriate professional and industry groups; representative of university, industry, labor, consumer and other public interest groups; and appropriate individuals. The section permits the Board to transfer appropriate funds to other Federal agencies to reimburse them for the use of their personnel, services, facilities, equipment and information.

Section 206. Compensation of members

Section 206 provides for compensation to Federal and Non-Federal members of the Board.

Section 207. Authorization of appropriations

Section 207 authorizes appropriations of $2,000,000 for FY 1989, $2,500,000 for each FY 1990 and 1991, and $3,000,000 for each FY 1992 and 1993.

SUBTITLE B—HUMAN GENOME RESEARCH AND DEVELOPMENT

Section 211. Findings

Section 211 sets forth the findings of the Congress related to human genome research and development: information related to locating and sequencing the genes of human chromosomes, as well as those of other organisms, will shed significant light on the basis for human diseases and developmental processes; better understanding of the genetic make-up of humans and the genetics of other organisms will enhance our ability to develop methods to

treat and prevent disease conditions; recent progress in biomedical research and technological advances have led to the ability of scientists to locate genes on specific human chromosomes; a number of Federal agencies are currently involved in research related to mapping and sequencing genes of the human genome, or the development of new technologies and instruments for this research and it is essential that agencies involved in human genome-related research coordinate their activities in order to efficaciously spend research funds, and to expeditiously further our understanding of human genetics.

Section 212. National Advisory Panel on the Human Genome

Section 212 establishes a National Advisory Panel on the Human Genome (the "Panel") to advise the Board on matters involving mapping and sequencing the human genome. The Panel will coordinate national activities to assure the creation of maps of human chromosomes and DNA of other organisms that will be used as powerful research tools for biomedical research, and the development of new tools to analyze DNA. The section describes the membership of the Panel (3 Directors of Agencies, and 1 Secretary—NIH, NLM, the National Science Foundation, and the Department of Energy (DOE), respectively; and 10 appointed members), and directs the Panel to be cochaired by the Secretary of DOE and the Director of NIH. The section sets forth specific functions of the Panel to include: identifying the optimal plan for mapping and sequencing the human genome, using information and recommendations from prior reports for guidance; determining research and development objectives that will assure the Nation's leadership in human genome research; establishing standards for collecting and storing data and materials, and assuring quality scientific and technical work; assessing the need for common research resources; monitoring pertinent research programs funded by Federal agencies and private sources; identifying commercial opportunities emerging from national research programs; overseeing interagency cooperation through joint funding of research resources, data-sharing, joint sponsorship of meetings, and communication of annual budget plans; assessing the need and benefit of international cooperation in human genome mapping and sequencing activities; evaluating the ethical implications related to human genome mapping and sequencing developments; and evaluating patent rights and ownership of data issues related to the human genome, and providing advice to interested Federal agencies, the scientific community, and the private industry.

IX. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART I—BIOMEDICAL ETHICS

SEC. 381. (a)-(d) * * *

(e) [To enable the Board and the Committee to carry out their functions there are authorized to be appropriated $2,000,000 for fiscal year 1986, $2,500,000 for fiscal year 1987, and $3,000,000 for fiscal year 1988.] *To enable the Board and the Committee to carry out their functions, there are authorized to be appropriated $2,000,000 for fiscal year 1989, $2,500,000 for fiscal year 1990, and $3,000,000 for fiscal year 1991.*

TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART D—NATIONAL LIBRARY OF MEDICINE

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SUBPART 3—NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

SEC. 478. NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION.

(a) ESTABLISHMENT.—To focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology research by information systems, and to support and enhance the development of new information technologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the "Center") in the National Library of Medicine.

(b) FUNCTIONS.—Through the Center and subject to section 465(d), the Secretary shall—

(1) coordinate the design, development, implementation, and management of automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human, animal, and plant molecular biology, biochemistry, and genetics;

(2) conduct a research program into advanced methods of computer-based information processing capable of representing and analyzing the vast number of biologically important molecules and compounds using Center capabilities, as well as those in Federal, university, and private research laboratories;

(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) and methods described in paragraph (2);

(4) coordinate the efficient input of information regarding biotechnology from all government agencies and as well as

agency grantees and contractors, and where applicable, inform granting agencies of duplications of research efforts;

(5) encourage the input of information regarding biotechnology from the private sector, including professional scientific societies, foundations, and companies;

(6) coordinate biotechnology research information provided by the center and other sources, including the biotechnology industry, other government agencies, and the private sector (including professional scientific societies, foundations, and companies); and

(7) coordinate, to the maximum extent practicable, efforts to gather biotechnology information on an international basis.

(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of the fiscal years 1989 through 1993. Funds apporopriated under this subsection shall remain available as specified in appropriations acts.

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